REMARKS

Reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

Claims 1, 13, and 14 are under consideration in this application. Claims 15, and 17-30 have been withdrawn from consideration.

Response to Rejections Under 35 U.S.C. §103

Claims 1, 13, and 14 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Goodman et al. (PCT International Publication No. WO/27960) in view of Fleischer (1999, Abstract Only) or Fleischer (1999); and Miller et al. (1980 Abstract Only) and further over Canadian Patent 2161737 ("MacKay et al."). The rejection is respectfully traversed.

Applicants have previously shown that the prior art represented by Goodman et al., the Fleischer Abstract (1999) or Fleischer (1999), and Miller et al. did not teach or suggest a method of treating atopic dermatitis using a nitroimidazole derivative, "wherein a concentration of the nitroimidazole derivative is 1.5 to 5 % by weight" as recited in claim 1. The Examiner responded by citing Canadian Patent 2161737 ("MacKay et al.") and alleging that MacKay et al. teaches the use of the topical formulation of metronidazole at the concentration of 5% topical suspension for the treatment of inflammatory skin conditions. However, the disclosure of MacKay et al. does not cure the deficiencies that have been previously noted in the prior art.

At first it must be noted that MacKay et al. is directed to a gel for the treatment of rosacea and acne, not atopic dermatitis. See, MacKay et al. at Abstract. As applicants have

repeated pointed out and demonstrated with evidence that, although the myriad forms of dermatitis are sometimes referred to generically, they are not the same in either etiology or treatment. To the extent that some authors might fail to note the distinctions between different forms of dermatitis in every instance, persons of ordinary skill in the art would understand that any generalizations between rosacea and acne on the one hand and atopic dermatitis on the other hand would be in error. Atopic dermatitis, which is treated by the presently claimed methods, has been recognized as having an etiology that is different than either rosacea or acne and has proven to be particularly difficult to treat compared to either rosacea or acne. For this reason, the teachings of MacKay et al. are simply not relevant to the present methods.

The statement upon which the Examiner has relied was presented by MacKay et al. particularly in regard to treatment of rosacea. MacKay et al. describes in the "background of the invention" section as follows: "[C]oncerns over the possible toxicity associated with long term [oral] therapy prompted the development of topical formulations such as 1% cream, 0.75% water based gel, and even a 5% topical suspension." (see page 1, lines 25 to 27). However, MacKay et al. continues to describe as follows: "[N]one of these formulations took into account that the sun, among other environmental factors like the wind or cold, could produce a dermal dystrophy in inherently susceptible individuals which could be the source of the symptoms observed in rosacea. - - -Several papers report that patients with rosacea complained that exposure to sun made their condition worse." (see page 3, line 26 to page 4, line 3, emphasis added). "Since it is well established that sunlight makes rosacea worse, it would be beneficial to patients with rosacea to apply sunscreens to block the UV radiation from damaging the skin further by exacerbating rosacea." (see page 4, lines 5 to 8, emphasis added). MacKay et al. explains the purpose of the disclosure as follows: "It is therefore an

object of the invention to provide a topical composition for the treatment of rosacea which includes sunscreens to block UV radiation from damaging the skin further, preferably the sunscreen block UV-A and UV-B radiation." (see page 4, lines 9 to 12, emphasis added).

MacKay et al. is silent with respect to the treatment of atopic dermatitis, which is the disease to be treated by the present invention. Furthermore, it must be noted that Mackay et al. does not actually suggest the use of any gel having 5% metronidazole. Rather MacKay et al. teaches a 1.0% metronidazole gel with sunscreen for the treatment of rosacea and acne. (see page 9, line 23, and page 12, line 16) Thus, the single reference in the background to the prior existence of a 5% suspension does not constitute any suggestion to actually use that suspension in the treatment of even rosacea let alone atopic dermatitis. consequently, MacKay et al. cannot be construed to have provided any basis to try using a higher concentration or to treat any other form of dermatitis. It remains a fact that the surprising effectiveness of the presently claimed methods in treating atopic dermatitis could not have been predicted from the prior art.

As shown in Test Examples 1 to 8 in the present specification, the present inventors were the first to succeed in the treatment of atopic dermatitis by use of a preparation containing 1.5 to 5% by weight of nitroimidazole derivative. Because of the recognized difficulty of treating atopic dermatitis and the general view in the art at the time that no more that about 0.75 - 1 % of a nitroimidazole derivative should be used, the results disclosed by the present inventors were not expected in the art. None of the cited references separately or together would have predicted the results obtained by the inventors. Therefore, the present invention would not have been obvious from the cited references.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this Amendment and reply, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

The Director is hereby authorized to charge any appropriate fees that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: May 18, 2009

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